

In The Specification:

The paragraph starting at line 1 on page 10 is amended as follows:

Figure 14 is Figures 14A, and 14B when considered together
comprise a generally perspective, exploded view of the assembly shown in
Figure 4. (hereinafter collectively referred to as Figure 14)

In The Specification:

Following the paragraph starting at line 1 on page 10, add the following new paragraph:

Figure 14B is an end view of the snap together housing component shown in the lower left hand portion of Figure 14A.

In the Specification:

The paragraph starting at 3 on page 10 is amended as follows:

Figure ~~14A~~ is a view taken along lines ~~14A-14A~~ 14-C-14C of Figure ~~14~~ 14B.

In the Specification:

The paragraph starting at line 6 on page 12 is amended as follows:

~~Figure 37 is Figures 37 and 37A when considered together comprise a~~
generally perspective, exploded view of the assembly shown in figure 30
(hereinafter collectively referred to as Figure 37)

In the Specification:

Following the paragraph starting at line 6 on page 12, add the following new paragraph:

Figure 37B is an end view of the snap together housing component shown in the lower left hand portion of Figure 37A.

In the Specification:

The paragraph starting at line 8 on page 12 is amended as follows:

Figure ~~37A~~ 37C is a view taken along lines ~~37A-37A-~~37C-37C of Figure ~~37~~ 37B.

In the Specification:

The paragraph starting at line 14 on page 13 is amended as follows:

~~Figure 48 is~~ Figures 48 and 48A when considered together comprise
a generally perspective exploded view of the assembly shown in Figure 41
(hereinafter collectively referred to as Figure 41).

In the Specification:

Following the paragraph starting at line 14 on page 13, add the following new paragraph:

Figure 48B is an end view of the snap together housing component shown in the lower left hand portion of Figure 48A.

In the Specification:

Following the paragraph starting at line 14 on page 13, add the following new paragraph:

Figure 48C is a view taken along lines 48C-48C of the Figure 48B.

In the Specification:

The paragraph starting at line 8 on page 15 is amended as follows:

~~Figure 63 is~~ Figures 63 and 63A when considered together comprise a generally perspective, exploded view of the assembly shown in figure 52 (hereinafter collectively referred to as Figure 63)

In the Specification:

Following the paragraph starting at line 8 on page 15, add the following new paragraph:

Figure 63B is an end view of the snap together having component shown in the lower left hand portion of figure 63A.

In the Specification:

The paragraph starting at line 10 on page 15 is amended as follows:

Figure ~~63A~~ 63B is a view taken along lines ~~63A-63A~~ 63B-63B of Figure ~~63~~ 63B.

In the Specification:

The paragraph starting at line 11 on page 16 is amended as follows:

~~Figure 75 is Figures 75 and 75C when considered together comprise a~~
generally perspective exploded view of the assembly shown in Figure 67.
(hereinafter collectively referred to as Figure 75)

In the specification:

The paragraph starting at line 13 on page 16 is amended as follows:

Figure 75A is a view taken along lines 75A-75A of Figure ~~75~~ 75C.

In the Specification:

The paragraph starting at line 9 on page 17 is amended as follows:

Figure 82 is a ~~rear projected view taken along lines 82-82 of Figure 80~~
~~manifold of the rate control assembly shown in Figure 80.~~

In the Specification:

Following the paragraph starting at line 12 on page 17 add the following paragraph:

Figure 83 is a view taken along lines 83-83 of Figure 80.

In the Specification:

The paragraph starting at line 14 on page 17 is amended as follows:

Figure 83A is a side elevational view of the rate control assembly shown in Figure 77 as it appears in a sealably interconnected configuration.

In the Specification:

The paragraph starting at line 9 on page 21 is amended as follows:

~~Figure 106 is Figures 106 and 106B when considered together~~
comprise a generally perspective, exploded view of the assembly shown in Figure 99 (hereinafter collectively referred to as Figure 106)

In the Specification:

Following the paragraph starting at line 9 on page 21 add the following new paragraph:

Figure 106C is an end view of the snap together housing component shown in the lower left hand portion of Figure 106B.

In the Specification:

The paragraph starting at line 1 on page 36 is amended as follows:

Referring to figures 11 and 12, disabling means, shown here as a disabling shaft 164 that is telescopically movable within a passageway 166 formed within housing portion 54a functions to irrevocably disable the device and render it inert. More particularly, shaft 164 has a distal end 164a, which, upon insertion of the shaft distal end 164a into bore 164c (figure 35 ~~12~~), will block fluid flow through passageway 118. A friction fit retainer 164b normally holds shaft 164 in the retracted position (figures 12 and 14). As shown in figure 8, a receptacle bore 164c is provided for receipt of shaft 164.

In the Specification:

The paragraph starting at line 5 on page 40 is amended as follows:

Turning particularly to figures 30 and 37, each of the shell vials 188 and 192 can be seen to be of the same construction as the shell vial illustrated in figure 8A and as earlier described herein. After removal of the vial cover 201, which forms a part of the third portion of housing 174 (figures 30 and 37), vials 188 and 192 can be inserted into chambers 186 and 190 respectively. As the fill vials are so introduced and the plungers 102 thereof are threadably interconnected with ends 194a of supports 194, the sharp ends of the elongated needles 198 will pierce the central walls 102a of the elastomeric plungers. Continuous pushing movement of the vials into chambers 186 and 190 will cause the structural supports 194 to move the elastomeric plungers inwardly of the vial chambers. As the plungers move inwardly of the vial, the fluid contained within the vial chambers will be expelled there from into the hollow elongated needles 198. As best seen in figure 30, the fluid will then flow past umbrella type check valves 106 and into passageways 204 formed in third portion 180 of the apparatus housing. From passageway 204 the fluid will flow into passageway 182 and then into reservoir 58 of the bellows component 56 via inlet channel 60 (figures 30,

31, and 37). It is to be understood that the vials 188 and ~~190~~ 192 can contain the same or different medicinal fluids and can be introduced into their respective chambers either one at a time, or simultaneously.

In the Specification:

The paragraph starting at line 10 on page 43 is amended as follows:

As to the septum fill means, as illustrated in figure 41, third portion 220 includes a fluid passageway 222 which is in communication with inlet 60 of fluid reservoir 58. Proximate its lower end 222a, fluid passageway 222 communicates with a cavity ~~214~~ formed within the third portion 220 of the housing. Disposed within cavity ~~214~~ is a pierceable septum 84 that comprises a part of the septum fill means of this latest form of the invention. As before, elastomeric septum 84 is held in position by a retainer 84a and is pierceable by the needle of the syringe which contains the medicinal fluid to be dispensed and which can be used in a conventional manner to fill or partially fill reservoir 58 via passageway 222.

In the Specification:

The paragraph starting at line 1 of page 48 is amended as follows:

With regard to the fill means of this latest form of the invention, which is carried by the third portion 248 of the outer housing, as before, this important fill means functions to fill the reservoir 58 with the fluid to be dispensed. This fill means here comprises the previously described septum fill means, which is identical to that previously described, and also includes the previously mentioned, first and second cartridge type vial fill vials generally designated in figure 52 by the numerals 252 and ~~254~~ 272 respectively. As to the septum fill means, as illustrated in figure 52, third portion 248 includes a fluid passageway 256 which is in communication with inlet 60 of fluid reservoir 58. Proximate its lower end 256a, fluid passageway 256 communicates with a cavity 258 formed within the third portion 248 of the housing. Disposed within cavity 258 is an elastomeric pierceable septum 84 that comprises a part of the septum fill means of this latest form of the invention. As before, septum 84 is held in position by a retainer 84a and is pierceable by the needle of the syringe which contains the medicinal fluid to be dispensed and which can be used in a conventional manner to fill or partially fill reservoir 58 via passageway 256.

In the Specification:

The paragraph starting at line 5 on page 49 is amended as follows:

With respect to second reconstitution cartridge fill vial ~~254~~ 272, this fill vial, which is more clearly illustrated in figures 53 and 54 of the drawings, comprises a container of special design that uniquely contains a lyophilized drug 262 that is separated from a reconstituting fluid 264 by a barrier stopper 266 (figure 53). Lyophilized drug 262 can, by way of example, comprise anti-infectives, cardiac drugs or various other types of beneficial agents.

In the Specification:

The paragraph starting at line 14 on page 49 is amended as follows:

Considering in more detail the novel bypass cartridge assembly ~~254~~
272, as best seen in figure 53, this cartridge assembly includes a vial 272
that is sealed at one end by elastomeric plunger 271 and at the other end by a
pierceable septum 274 (figures 52 and 53). Formed intermediate the ends of
vial 254 is a raised outer wall portion 272a which after installation of the
cartridge permits fluid 264 to bypass a barrier stopper 266 as the barrier
stopper is urged inwardly of the container by pressure exerted thereon by the
fluid 264, which is being pushed by plunger/stopper 271 resulting from force
exerted on pusher element member ~~276~~ 270. Fluid 264 exerts pressure on
barrier member 266 as a result of the inward movement of plunger ~~270~~ 271
by the pusher member as the vial is fully mated with the apparatus housing.

In the Specification:

The paragraph starting at line 6 on page 50 is amended as follows:

A continued inward pressure exerted on plunger 271 will cause fluid 264 to flow past barrier member 266 via the internal passageway defined wall portion 272a so as to reconstitute the lyophilized drug 262. A continued pressure exerted on plunger 271 by the pusher member will cause the reconstituted drug formed by the fluid 264 which has been intermixed with drug 262 to flow through a hollow cannula 240 past check valve 106, into a stub passageway ~~277~~ 282 and then into a passageway 256 and finally into the device reservoir 58.

In the Specification:

The paragraph starting at line 6 on page 56 is amended as follows:

As best seen by referring to figure 80, each of the flow rate control plates is provided with an elongated micro channel of a particular configuration. These micro-flow channels can be formed in various ways known to those skilled in the art. For example, U. S. Patent No. 6,176,962 issued to Soane et al. describes methods for constructing micro channel structures for use in micro fluidic manipulations. Similarly, International Publication W0 99/5694A1 describes such methods. When the rate control plates are assembled in the manner shown in figures 80 and ~~83~~ 83A, it is apparent that the micro channel formed in each of the rate control plates will cooperate with the adjacent planar surface of the next adjacent rate control plate to form a fluid flow control channel through which the fluid flowing into inlet 318 can controllably flow. As indicated in the drawings, one end of each of the micro channels is in communication with the inlet port 318 of the inlet manifold 316 via a center port 319 and the other end of each of the micro channel is in communication with a selected one of the circumferentially spaced outlet ports provided in the outlet manifold 320. More particularly, as can be seen by referring to figures 80, 81 and 84 of the drawings, outlet 322a of rate control plate 322 is in communication with

outlet 341 of outlet manifold 320; outlet 324a of rate control plate 324 is in communication with outlet 342 of outlet manifold 320; outlet 326a of control plate 326 is in communication with outlet 343 of manifold 320; outlet 328a of control plate 328 is in communication with outlet 344 of outlet manifold 320 and outlet 330a of rate control 330 is in communication with outlet 345 of outlet manifold 320, and. outlet 332a of rate control plate 332 is in communication with outlet 346 of outlet manifold 320. In similar fashion, outlet 334a of rate control plate 334 is in communication with outlet 347 of outlet manifold 320; outlet 336a of rate control plate 336 is in communication with outlet 348 of manifold 320 and outlet 338a of control plate 338 is in communication with outlet 349 of outlet manifold 320 and outlet 340a of rate control plate 340 is in communication with outlet 350 of outlet manifold 320.

In the Specification:

The paragraph starting at line 14 page 59 is amended as follows:

When the selector knob is in the desired position and pressure is released on indexing shaft 393, spring 391 (figure 67) will urge finger 389 of the indexing means of the invention into locking engagement with one of the indexing cavities 379 (figure 74) thereby placing a selected one of flow control channels of a flow rate control plate in communication with flow passageway 378a (figures ~~67~~ 67A and 76) of the flow control knob. As the fluid flows outwardly of the apparatus due to the urging of the stored energy means or spring member 67, the bellows structure 310 will be collapsed and at the same time member 69 will travel inwardly of the housing. Member 69, which forms a part of the volume indicator means of the invention, includes a radially outwardly extending indicating finger 110 that is visible through a volume indicator window 160 that is provided in a second portion 308 of the apparatus housing and also comprises a part of the volume indicator means of the invention. Indicia 161, which are provided on indicator window 160 (figure 64), function to readily indicate to the caregiver the amount of fluid remaining within fluid reservoir 312 at any point in time.

In the Specification:

The paragraph starting at line 12 page 60 is amended as follows:

Referring particularly to figures 67, 76 and 77, a selector knob 378, which comprises a part of the selector means of the invention, is sealably connected to outlet manifold 320 by means of O-Rings "O" and is rotatable with respect thereto. As previously mentioned, this novel selector means of the invention functions to control the flow of fluid from outlet manifold 320 toward the administration set 343. More particularly, as illustrated in figures 93, 93A and 93B, selector knob 378 is provided with a circumferentially extending flow channel 378a which is selectively in communication with stub passageways 375 of outlet manifold 320 depending upon the position of the selector knob. As illustrated in figures 93A and 93B, the rearwardly extending, generally cylindrical, reduced diameter portion 378c of the control knob, which circumscribes the outlet manifold 320, is provided with a circumferentially extending, elastomeric band 382 which prevents fluid leakage between the outlet manifold and the flange 378c. Outlet manifold 320 is also provided with a similarly configured, circumferentially extending, elastomeric band 384. As indicated in figure 93A, elastomeric band 384 has an opening 384a that is in alignment with fluid outlet passageway 380 formed in the first portion 306 of the outer

housing (see also figure 67). Elastomeric band 382 also has an opening 382a which is aligned with a radially extending flow passageway 378b formed on portion 378c of the control knob, which, in turn, is in communication with circumferentially extending flow channel 378a (figure 93A). With this construction, when the control knob 378 is rotated to a position such as that illustrated in figure 93A, wherein one of the outlets of the outlet manifold ~~322~~ 320 is in alignment with the opening 382a formed in the elastomeric band 382, fluid can flow from that outlet and into circumferentially extending flow channel 378a. From flow channel 378a, the fluid can flow into radially extending passageway 378b, through opening 384a and into passageway 380. From passageway 380, the fluid can flow onwardly into the dispensing means or administration set 343. The rate at which the fluid flows toward the administration set depends, of course, upon which rate control plate outlet is in communication with radial passageway 378b formed in the control knob. By way of example, with the control knob 378 in the position shown in figure 93A, it is to be observed that the fluid flowing toward the administration set is flowing from outlet 322a of rate control plate 322 and will flow at a rate determined by the configuration of rate control micro channel 354 (see figures 80 and ~~88~~ 80A).

In the Specification:

The paragraph starting at line 3 page 64 is amended as follows:

Turning particularly to figures 99 through 101, the alternate form of the flow control means of the apparatus of this latest form of the invention is there shown. As before, this alternate flow control means functions to precisely control the rate outwardly to fluid flow from reservoir 312 and toward the patient. In this latest form of the invention, the flow control means comprises a flow rate control assembly generally designated in the drawings by the numeral 404. This novel flow rate control assembly here comprises an inlet manifold 406 having an inlet port 408 that is in communication with the outlet 312a of the fluid reservoir 312 and a fixedly mounted, outlet manifold 410 that is interconnected with inlet manifold 406 by means of a pair of interconnected plates 412 and 414. Plate 412 is identical in construction and operation to the previously describe flow rate control plate 322 and is provided with a micro channel 354 (see also figures 80 and ~~81~~ 80A). Plate 414, on the other hand, is a generally cylindrically shaped plate having planar front and rear surfaces. With this construction, the rear surface of plate 414 cooperates with the micro channel 354 of plate 412 to provide a closed flow control channel which controls the rate of fluid flow from the reservoir toward the administration set of the apparatus of the

invention. As indicated in the drawings, outlet manifold 410 has an outlet passageway 416 that is in communication with the outlet port of rate control plate 412.

In the Drawings:

Amend the following Drawing Sheets:

1. Sheet 9 of 68
2. Sheet 20 of 68
3. Sheet 24 of 68
4. Sheet 28 of 68
5. Sheet 36 of 68
6. Sheet 49 of 68
7. Sheet 52 of 68

Enclosed herewith for each amended sheet is a “Replacement Sheet” and an “Annotated Marked Up Drawings” sheet showing the changes made in the figure drawings by interlineation.